

REMARKS

Claims 124-130 and 143-149 are pending in the application. Applicants amend claims 124, 125, and 130 to recite "150°C or above" and claim 128 to recite a swell ratio of "5 or less", for the reasons discussed herein. No new matter is introduced. The office action is discussed below:

Response to Arguments and Anticipation Rejection:

On pages 2-5 and 6-7 of the Office Action, the examiner states that the arguments, filed on January 10, 2008, are not persuasive and maintained the rejection. Applicants respectfully disagree with the examiner, traverse the rejection, and submit the following in order to assist the examiner further distinguishing the claimed invention from the cited references.

Claims 124-130 and 143-149 were rejected because the examiner could not understand or assume inherency for the claimed process and believes that no extrinsic evidence has been made of record in the instant case to support inherency for descriptive matter to support recitations in the instant claims.

Applicants submit that instant specification has support for a method of crosslinking by irradiation and heating at 150°C or above after each irradiation, which inherently involves "melting" after irradiation, as recited in the claims.

Applicants note that the examiner is trying to limit the claims in view of certain embodiments of the specification and not allowing the steps that are inherently disclosed in the specification as understood by the skilled person. Applicants invite the examiner to consider the dictates of the MPEP § 2163.07 and § 2164 (Rev. 6, September 2007 at 2100-192 to 2100-193) that:

"By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443

F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973)."

And that: "Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention."

Applicants refer the examiner to the specification for support regarding the inherent disclosure. See Example 6 at pages 44-46, for example, although the thermal treatment was continued through the irradiation process of cross-linking, it is inherent that the UHMWPE is heated to melt after each passage through the conveyor belt, that is, after each cycle of irradiation, which includes heating in between two "melting" (that is, before and after each irradiation dose or a total dose of irradiation). It would be obvious to one skilled in the art and to those who are familiar with van de Graaff generator that specimens are taken out of the belt and reintroduced to continue on the irradiation process to achieve the desired total dose (in this case a total of 20 Mrad at a dose rate of 2.5 Mrad per pass). It also would be apparent to one skilled artisan that after each passage the UHMWPE is taken out of the belt and melted when reintroduced to the belt to continue on heating (to melt) and irradiation cycle till the desired total dose is achieved.

Clearly, the polymer according to the claimed invention is produced by melting, cross-linking at least twice by irradiation and thermally treating after each irradiation, that is by "melting" and/or "subsequent melting" throughout the process. And, steps of "melting" and/or "subsequent melting", also in view of Shen *et al.*, are inherent to the instantly claimed process.

Regarding "remelting", applicants refer to a recent Office Action in a related case (see U.S. App. No. 11/184,803, MERRILL *et al.*, Office Action mailed on March 21, 2008, pages 2 and 5, for example), in which the examiner agreed that the phrase "subsequent melting" means melting (that is, heating above the melting temperature, in this case, 150°C or above) after irradiation and the phrase is equivalent to the meaning of "remelting", based on the term "remelting" as defined by Shen *et al.*, and to the general understanding that the prefix "re" before "melting" means repeating the heating for melting.

The claimed UHMWPE is produced by melting, cross-linking at least twice by irradiation and thermally treating after each irradiation, that is by "remelting" and/or "subsequent melting" throughout the process. And, steps of "remelting" and/or "subsequent melting", in view of Shen *et al.*, are inherent to the instantly claimed process. In fact, it is the examiner who suggested replacing the term "remelting" with "subsequent melting" in a related case (see U.S. App. No. 11/184,803, MERRILL *et al.*, Office Action mailed on March 21, 2008, pages 2 and 5). See scanned passages below:

Applicant reiterates the argument that "subsequent melting" in the instant specification is equivalent to "remelting" as defined by Shen *et al.* This argument will be considered when the term "remelting" which is not found within the instant specification is replaced with the phrase "subsequent melting" in the instant claims.

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With respect to claims 124-140: The examiner has not found any disclosure of a process of "remelting" the crosslinked polymer, wherein the crosslinked polymer is obtained by irradiating a preformed polymer in the solid state, as set forth in claim 124. Applicant discloses a process of melting UHMWPE followed by irradiation and several variations of a process of irradiating an UHMWPE followed by "subsequent melting". See page 18. It is suggested that applicant replace the term "remelting" with "subsequent melting" for the reasons set forth herein above.

Regarding the arguments that the instant specification discloses a method that inherently involves crosslinking by irradiation in steps with heating above the melt between the irradiations steps, applicants refer to an expert opinion/evidence submitted in the related case (see U.S. App. No. 11/184,803, MERRILL *et al.*, declaration of Dr. Orhun Muratoglu, filed on September 22, 2008, pages 2-4 in sections 4, 7, and 8) that this method is inherent to what is explicitly disclosed in the instant specification. Specifically, on page 4, section 7, of the declaration, Dr. Muratoglu clarified that "specification discloses a method that inherently involves crosslinking by irradiation in steps with heating between the irradiations steps."

On page 3 of the Office Action, regarding the declaration pursuant to 37 C.F.R. § 1.131 evidencing completion of the claimed invention prior to January 20, 1995, the examiner asserts that the declaration supports that the methods comprising irradiation followed by "subsequent melting" were disclosed in Application Serial No 08/726,313, filed 10-02-1996 and in Application Serial No. 08/798,638, filed 02-11-1997. Applicants disagree with the examiner and point out that the present application has the same parent as the US Application Serial No. 10/197,263. Therefore, the declaration in the parent case shows that the completion of the disclosed investigation is prior to January 20, 1995, which is also applicable to the instantly claimed subject matter.

The examiner contends that the declaration provides evidence of reduction to practice of the disclosed "MIR" method before January 20, 1995, and there is no evidence to show reduction to practice of the various methods disclosed October 2, 1996 comprising irradiation and subsequent melting, such as "IR-SM", before January 20, 1995. Again, applicants disagree with the examiner and refer to the Declaration Exhibit 1, pages 1-2, Exhibit 3, Experiment 2 for various methods of irradiations and subsequent heating steps, for example.

On page 3 of the Office Action, the examiner agreed that Experiment 2 in Exhibit 3 shows a sequence of heating and irradiating a sample to achieve a total radiation dose (50 Mrads). However, the examiner opined that there is no "subsequent melting" step following the irradiation dose of 50 MRads, and Experiment 2 does not include a heating/melting step after (subsequent to) the final irradiation dose of 50 MRads. Applicants also disagree with the examiner and point out that the step by step process is an example of irradiation and subsequent heating above the melt. The examiner did not consider embodiments of the specification that disclose experiments including the step of subsequent heating above the melt, for example, for a total dose of 20 MRads, see Example 3, Experiment 2, which requires eight passes under the e-beam and subsequent heating above the melt after each pass. The examiner considered only one total dose (50 MRads) and tried to limit the scope of the invention. The examiner is requested to consider the specification to its entirety.

Claim Interpretation and Effective Filing Date:

On pages 4-5 of the Office Action, the examiner interprets claims 124-130 and 143-149 to recite that the irradiation and subsequent melting method ("IR-SM") first disclosed in SN 08/726,313, filed October 2, 1996. Thus, the examiner opined that claims 124-130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of October 2, 1996, and February 13, 1996 is the filing date of the priority application SN 08/600,744. Therefore, the examiner considers that the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the October 2, 1996 filing date of SN 08/726,313. Applicants disagree with the examiner and submit, as discussed above and as evidenced by the declaration and the Exhibits, that the instantly claimed embodiment wherein irradiation is followed by melting, i.e. "IR-SM", was reduced to practice prior to January 20, 1995.

On page 5 of the Office Action, the examiner also asserts that claims 128-129 are not supported by the disclosure of SN 08/600,744, does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE, thus, claims 128-129 are not entitled to the February 13, 1996. Applicants disagree and refer to the original specification, see for example, Example 4, Tables 2 and 6; and Example 11, Tables 8 and 11 for support.

In view of the above clarifications, applicants submit that Shen *et al.* (the '900 patent) and Hyon *et al.* (the '626 patent), are not prior art to the claimed invention. Accordingly, withdrawal of the anticipation rejection is solicited.

Indefiniteness Rejection:

On page 6 of the office action, the examiner has rejected claims 124-125, 128, and 130 under 35 U.S.C. 112, second paragraph, allegedly as being indefinite for using the term "about" and "or above" or "or less". In order to expedite the prosecution, applicants amend claims 124, 125, and 130 by deleting the phrase "a temperature about", and claim 128 by deleting the term "about" without prejudice or disclaimed.

Withdrawal of the rejection is therefore requested.

Double Patenting Rejections:


On pages 8-10 of the office action, the examiner has maintained the provisional obviousness-type double patenting rejection of the claims and alleged as being directed to the same invention as the claims of co-pending application serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089, and 10/197,263.

Applicants reiterate, since a notice of allowability has not been issued for any of the application serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089, and 10/197,263, the merits of this provisional rejection need not be discussed with the examiner at this time. See MPEP § 822.01.

REQUEST

Applicants submit that claims 124-130 and 143-149 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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Date

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